OCT - 1 2001

K012335

510(k) Summary
for
Browne Metrex 1.8% Glutaraldehyde Indicator for METRICIDE® 28 and METRICIDE PLUS 30® Solutions

1. SUBMITTER NAME AND ADDRESS

Mr. Alan Charlton
Albert Browne Ltd.
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

Contact: Alan Charlton
Telephone number: 44 116 276 8636

2. DEVICE NAME

Proprietary Name: Browne Metrex 1.8% Glutaraldehyde Indicator for Metricide® 28 and Metricide Plus 30® Solutions
Common/Usual Name: Browne Metrex 1.8% Glutaraldehyde Indicator
Classification Name: Physical/Chemical Sterilization Process Indicator

3. PREDICATE DEVICE

Browne GA Indicator (K922481, Albert Browne Ltd.)

4. INTENDED USE

The Browne Metrex 1.8% Glutaraldehyde Indicator for Metricide 28 and Metricide Plus 30 Solution (Browne Metrex 1.8% Glutaraldehyde Indicator) is a glutaraldehyde concentration monitor for use in glutaraldehyde-containing germicide solutions with a minimum effective concentration (MEC) of 1.8% glutaraldehyde.

The Browne Metrex 1.8% Glutaraldehyde Indicator is dedicated for use with Metricide 28 and Metricide Plus 30 Solutions.

5. DEVICE DESCRIPTION

The Browne Metrex 1.8% Glutaraldehyde Indicator for Metricide 28 and Metricide Plus 30 Solution and the substantially equivalent device are chemical indicator strips intended to monitor the concentration of glutaraldehyde in glutaraldehyde-containing germicide solutions. The devices indicate, via a color change, if the germicide concentration exceeds the MEC for the solution.

The Browne Metrex 1.8% Glutaraldehyde Indicator consists of a polypropylene strip with an indicator pad on one end. The indicator pad is impregnated with an indicator solution that changes color from yellow to purple in liquid chemical germicides with a glutaraldehyde concentration above the MEC of 1.8%.

6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Browne GA Indicator are similar to that of the Browne Metrex 1.8% Glutaraldehyde Indicator described in this submission. Both devices are non-sterile, disposable strips containing an indicator pad impregnated with an indicator solution that changes color in a germicide solution at the appropriate glutaraldehyde concentration.

The mechanism of action for inducing a color change is identical for the Browne Metrex 1.8% Glutaraldehyde Indicator and the Browne GA Indicator. Glutaraldehyde reacts with sodium sulfite in the test strip to form a sulfite addition product and an equivalent amount of base. If sufficient glutaraldehyde is present, the increase in pH causes a color change in the pH indicator.

The indicator color is dependent upon the glutaraldehyde concentration of the germicide solution, and the time after exposure when the results of the test are read, as described in the table below.

Color Development for the Metrex 1.8% Glutaraldehyde Indicator Strip

Time(minutes)	Glutaraldehyde Concentration (%)		
	<1.8	1.8-2.1	>2.1
<1	yellow, purple/yellow		
1-2	yellow, purple/yellow	yellow, purple/yellow, purple	purple
>2	yellow, purple/yellow		

During the first 60 seconds after the test strip has been dipped into the Metricide 28 or Metricide Plus 30 Solution, the yellow test strip will begin to develop a purple color.

At 60 seconds (one minute), the strip will exhibit a uniform purple color (except for the top 2 mm of the strip) if the concentration of glutaraldehyde is >2.1. The strip will appear patchy purple/yellow or yellow if the solution contains <1.8% glutaraldehyde. In the concentration range of 1.8 to 2.1, the strip may appear yellow, purple/yellow, or purple.

From 60 to 120 Seconds (one to two minutes) the color of the strip is stable. A color reading must be taken during this time period for the results to accurately reflect the glutaraldehyde concentration of the Metricide 28 or Metricide Plus 30 Solution.

After 120 seconds (two minutes) the color of the strip regresses toward the original yellow color. The rate of regression is dependent on the glutaraldehyde concentration of the Metricide 28 and Metricide Plus 30 Solution being tested.

7. PERFORMANCE TESTING

The performance characteristics of the Browne Metrex 1.8% Glutaraldehyde Indicator were established by testing indicators in Metricide 28 and Metricide Plus 30 Solutions containing 1.8% and 2.1% glutaraldehyde. No false positives were recorded in solutions containing 1.8% glutaraldehyde, when the testing was performed according to the Instructions for Use. The data demonstrates that the Browne Metrex 1.8% Glutaraldehyde Indicator is an effective monitor for the glutaraldehyde component of the Metricide 28 and Metricide Plus 30 Solution with a glutaraldehyde MEC of 1.8%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Albert Browne Limited
C/O Ms. Cynthia J.M. Nolte
Staff Consultant
Medical Device Consultants
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K012335
Trade/Device Name: Browne Metrex 1.8% Glutaraldehyde Indicator for Metricide® 28 and Metricide Plus 30® Solutions
Regulation Number: 880.2800
Regulation Name: Browne Metrex 1.8% Glutaraldehyde Indicator
Regulatory Class: II
Product Code: JOJ
Dated: July 23, 2001
Received: July 24, 2001

Dear Ms. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

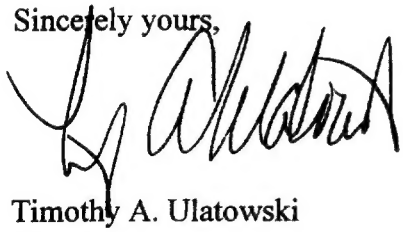
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012335

Device Name: Browne Metrex 1.8% Glutaraldehyde Indicator for Metricide® 28 and Metricide Plus 30® Solutions

Indications for Use:

The Browne Metrex 1.8% Glutaraldehyde Indicator for Metricide® 28 and Metricide Plus 30® Solutions (Browne Metrex 1.8% Glutaraldehyde Indicator) is a glutaraldehyde concentration monitor for use in glutaraldehyde-containing germicide solutions with a minimum effective concentration of 1.8% glutaraldehyde.

The Browne Metrex 1.8% Glutaraldehyde Indicator is dedicated for use with Metricide® 28 and Metricide Plus 30® Solutions.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012335

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)